RECEIVED
CENTRAL FAX CENTER
SEP 12 2006

REMARKS

Examiner Interview

Applicants thank Examiners Alstrum-Acevedo and Richter for their assistance during the interview on July 28, 2006. During that interview, claim amendments that distinguish the claimed invention from the prior art were discussed. Applicants respectfully submit that the amendments to the claims, set forth in the Listing of Claims, accurately reflect the outcome of those discussions and accordingly the claims are allowable over the cited art.

Amendments to the Claims

As requested by the Examiner, applicants respectfully set forth support for the claim amendments.

First, support for the amendments can be found throughout the application as originally filed. Specific support for the disintegrants can be found at least on page 15. Specific support for the nasal tissue irritant, and in particular sodium lauryl sulfate, can be found at least on page 12 in the section titled "Mucous Membrane Irritants and/or Nasal Passageway Tissue Irritants." Support for polyethylene oxide can be found at least on page 9.

Further, support for the "% recovery limitations" of claims independent claims 44 and 50 can be found at least on pages 11 and 12 of the application as originally filed.

Claim Rejections Under 35 U.S.C. § 112

Claims 10, 14, 33-34, 49 and 59 stand rejected under 35 U.S.C. § 112, second paragraph. These claims have all been cancelled, thereby rendering the rejection moot.

Furthermore, applicants' designation of the term "crospovidone" as a trademark in the specification on page 15 of the application was in error and applicants respectfully assert that the

term is generic and is not a trademark. Thus, to the extent any of the pending claims recite "crospovidone" applicants respectfully submit that the rejection is improper and request that the rejection be withdrawn.

Claim Rejections Under 35 U.S.C. § 102(e)

Claim 1-3, 5, 8, and 42 stand rejected under 35 U.S.C. § 102(e) as anticipated by Anderson et al. (U.S. Patent Application Publication Number 2003/0125347). Applicants have cancelled these claims, thereby rendering the rejection moot.

Claims 1-8, 12, 38, 44-47, 50-53 and 55 stand rejected under 35 U.S.C. § 102(e) as anticipated by Bartholomaus et al. (WO 04/037259). Applicants respectfully submit that claims 1-8, 12, 38, 45-47 and 51-53 and 55 have been cancelled, thereby rendering the rejection moot with respect to the cancelled claims.

With respect to claims 44 and 50, applicants have amended the claims to recite "a mixture" as well as specifically recite "polyethylene oxide." New claim 60 also recites these limitations. As discussed during the interview, these limitations distinguish the claimed invention from the Bartholomaus et al. reference. Accordingly, applicants respectfully request withdrawal of the rejection under § 102(e).

Claim Rejections Under 35 U.S.C. § 103

Claims 4, 6-7, 9-15, 38 and 44-59 stand rejected under 35 U.S.C. § 103 as obvious in view of Anderson et al. Claims 9-11, 13, 54 and 57 stand rejected under 35 U.S.C. § 103 as obvious over Bartholomaus et al. Lastly, claims 16 and 33-34 stand rejected as obvious in view of Anderson et al. in further view of Porter (U.S. Patent No. 4,175,119).

As set forth above, claims 4, 6-7, 9-16, 33-34, 45-49, 54 and 56-59 have been cancelled, thereby rendering the rejection of these claims moot. With respect to remaining amended claims 44 and 50 and new claims 60-111, applicants respectfully submit that the rejection does not apply to

these claims because claims 44, 50 and 60 recite claim features that are unobvious when the claimed invention is viewed as a whole.

The claimed features include:

a mixture including

(a) at least one opioid analgesic or a pharmaceutically acceptable salt, derivative, analog, homologue, or polymorph thereof, selected from the group consisting of alfentanil, buprenorphine, butorphanol, carfentanil, codeine, dezocine, diacetylmorphine, dihydrocodeine, dihydromorphine, diprenorphine, etorphine, fentanyl, hydrocodone, hydromorphone, β-hydroxy-3-methylfentanyl, levo-α-acetylmethadol, levorphanol, lofentanil, meperidine, methadone, morphine, nalbuphine, oxycodone, oxymorphone, pentazocine, pethidine, propoxyphene, remifentanil, sufentanil, tilidine and tramadol,;

(b) polyethylene oxide;

(c) at least one disintegrant selected from the group consisting of crospovidone, sodium starch glycolate, and croscarmellose sodium; and

(d) a nasal tissue irritant [or, in the case of claim 60, "sodium lauryl sulfate"]

As discussed during the examiner interview, the above recited combination of constituents yields a composition that provides unexpected results over known compositions. As also explained on page 12 of the application as filed, greater than 93% of abusable drug can be recovered from commercially available products such as immediate release and controlled release Oxycontin®. Comparatively, significantly less abusable drug is recovered from dosage forms of the present invention.

As evidenced in the specification, and in particular Figs. 1 and 2 as well as Examples 3, 4, 6, 9 and others, the present invention unexpectedly functions in a manner such that a large percentage of the total amount of opioid analgesic in the composition is unrecoverable when a composition of the invention is contacted with a solvent (e.g., water). The Figures and Examples show that

the amount of abusable drug that can be recovered from a composition of the claimed invention is significantly reduced.

Thus, dosage forms which employ a composition of the claimed invention significantly, and quite unexpectedly, reduce the abuse potential of the opioid analgesic drug or drugs included with the composition.

Accordingly, because the claimed invention recites limitations that are not suggested or disclosed in the cited art, and because the claimed invention provides unexpected results with respect to drug recovery, as shown in the application as filed, the claimed invention is unobvious over the cited art.

By virtue of the above provided claim amendments, and in accordance with the suggestion of the Examiner, applicants have amended claim 44, 50 and added new claim 60. The amendments render the rejections moot and place claims 44, 50 and 60 in a condition for allowance. Further, because claims 44, 50 and 60 are allowable, claims that depend there from are also allowable. Accordingly, claims 61-111 are also in a condition for allowance. Withdrawal of the rejections under 35 U.S.C. § 103 is hereby respectfully requested.

RECEIVED
CENTRAL FAX CENTER
SEP 12 2006

Summary

Applicants respectfully submit that the claims 44, 50 and 60-111 are now in a condition for allowance. Specifically, the rejections of the claims under 35 U.S.C. §§112, 102, and 103 have been addressed and overcome. Reconsideration and allowance of these claims is respectfully requested at the earliest possible date.

Respectfully submitted,

Vijai Kumar et al.

09/12/06
Date

By: _____

CHRISTOPHER I. HALLIDAY
Registration No. 42,621
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921
Telephone: (215) 963-5000
Direct Dial: (215) 963-5337
Facsimile: (215) 963-5001
E-Mail: challiday@morganlewis.com